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09/737,476	12/18/2000	Leo G.J. Frenken	P 0275850 T 7060C	9341

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EXAMINER	
COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	16

DATE MAILED: 09/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/737,476	Applicant(s) FRENKEN ET AL.	
	Examin r Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *8 and 10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-7 and 9, in Paper No. 13 is acknowledged. The traversal is on the ground(s) that the inventions of Groups II, IV and V involve a common search area, Class 800, subclass 288. The traversal is on the ground(s) that claim 13 (Group VI) should be included with the Group I claims, as the respective methods are sufficiently related to warrant examining of the claims of these two groups together. Additionally, it is asserted that Groups I, II, IV and V should be searched and otherwise considered together.

This is not found persuasive because while the search of Groups II, IV and V may overlap, their searches are not coextensive of each other. In this particular instance, a search of Group II is not coextensive with a search of Groups IV and V, since Group II requires a search for plants having enhanced levels of heavy chain immunoglobulins, which are not claimed in Groups IV and V. A search of Group IV is not coextensive with a search of Groups II and V, since Group IV requires a search for a method for increasing pathogen resistance in a plant, which is not claimed in Groups II and V. A search of Group V is not coextensive with a search of Groups II and IV, since Group V requires a search for a method for modulating plant metabolism, which is not claimed in Groups II and IV. Furthermore, a search of Group I is not coextensive with a search of Group VI, since Group VI requires a search for a method for preparing a heavy chain immunoglobulin, which is not claimed in Group I. Accordingly, claims 8 and 10-13 are withdrawn from consideration as being directed to nonelected inventions.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed April 30, 2001, Paper No. 4, is attached to the instant Office action.

Claim Objections

Claim 9 is objected to for depending from a claim directed to a nonelected invention. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 9 is drawn to progeny and hybrids of a plant prepared according to the method of claim 1.

The claimed invention lacks written description under current written description guidelines. The claim is drawn to progeny and hybrid plants having undisclosed identifying characteristics whereby only one parent is known. Applicant should note that no identifying characteristics are set forth for the progeny or hybrids. If the claimed progeny or hybrid plant

itself cannot be identified by characteristics clearly disclosed in the specification, then it would be impossible to determine whether or not a plant of unknown parentage is covered by the claim. Thus progeny or hybrid plants which are not disclosed by any identifying characteristics are not considered to be possessed by Applicant. Absent further guidance, there are insufficient relevant identifying characteristics to allow one skilled in the art to predictably determine the genotypic or phenotypic characteristics of the progeny or hybrid plants obtained. Breeding techniques can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring are highly unpredictable, especially in view of the fact that no identifying characteristics for the progeny or hybrid plants are disclosed in the specification or set forth in the claims. Accordingly, there is a lack of written description for the claimed progeny and hybrid plants, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the claimed genus (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2, 4 and 5 are indefinite in the recitation of "active fragment or derivative thereof". It is unclear what type of activity is intended, as antibodies are multifunctional proteins.

It is also unclear what features would be retained by a "derived" product. Additionally, in claim 1, does "thereof" refer to antibody, antibody fragment, or to plant ? In claim 2, does "thereof" refer to the immunoglobulin or the DNA sequence ?

Claim 1 is indefinite in the recitation of "desired cellular compartment". It is unclear what would make a cellular compartment desirable. It is also unclear which cellular compartments would be encompassed by the claims, as any cell would have a multitude of compartments, such as the nucleus, the golgi, the mitochondria, etc.

Claim 1 is indefinite in the recitation of "functionally equivalent thereto". It is unclear what type of functional equivalence is intended, as antibodies are multifunctional proteins. It is also unclear what the protein is functionally equivalent to. Does thereto refer to the heavy chain immunoglobulin ? the active fragment or derivative thereof ? the plant?

Claim 1 is indefinite in the recitation of "as appropriate". It is unclear under what circumstances provision of a peptide sequence capable of targeting an antibody would be "appropriate". Additionally, appropriate for what?

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 is missing the essential step of expressing an antibody. In the absence of antibody expression, the method of claim 1 will not result in antibody production. Furthermore, the claimed method does not result in antibody production as set forth in the preamble. Additionally, should said antibody or fragment or derivative thereof be targeted to the desired cellular compartment also?

Claim 2 is indefinite in the recitation of "obtainable from camelids". It is unclear what is obtainable from camelids - the heavy chain immunoglobulin ? the fragment ? the derivative thereof ? all three ?

Claim 2 is indefinite in the recitation of "obtainable". It is unclear in what way the DNA sequence is "obtainable". It is suggested that the claim be amended to recite "obtained".

Claims 2-6 are indefinite in the recitation of the indefinite article "a" before "method according to claim 1". It is suggested that the claims be amended to recite the definite article "the" before "method according to claim 1".

Claim 4 is indefinite in the recitation of "binds to a protein". It is unclear what binds to a protein - the heavy chain immunoglobulin ? the fragment ? the derivative thereof ? all three ?

Claim 5 is indefinite in the recitation of "binds to a plant or animal pathogen". It is unclear what binds to a plant or animal pathogen - the heavy chain immunoglobulin ? the fragment ? the derivative thereof ? all three ? It is also unclear whether the heavy chain immunoglobulin or active fragment or derivative thereof binds to a plant, or whether the heavy chain immunoglobulin or active fragment or derivative thereof binds to a plant pathogen.

Claim 6 is indefinite in the recitation of "binds to a plant hormone or metabolite". It is unclear what binds to a plant hormone or metabolite - the heavy chain immunoglobulin ? the fragment ? the derivative thereof ? all three ? It is also unclear whether the metabolite may be from any source, or whether the metabolite is a plant metabolite.

Claim 9 is indefinite in the recitation of the indefinite article "a" before "plant according to claim 7 or 8". It is suggested that the claim be amended to recite the definite article "the" before " plant according to claim 7 or 8".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 9 is drawn to seeds, fruits, progeny and hybrids, but is not limited to seeds, fruits, progeny and hybrids that comprise the construct that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single gene introduced into the parent plant would only be transferred to half of the seeds of that plant. In addition, given that there is no indication that there would be any other distinguishable characteristics of the claimed to seeds, fruits, progeny and hybrids, it is unclear whether the claimed to seeds, fruits, progeny and hybrids would be distinguishable from those that would occur in nature. See *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). The amendment of the claims to recite that the to seeds, fruits, progeny and hybrids comprise in their genome the construct that was introduced into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Owen et al. (Biotechnology, Vol. 10, pages 790-794, July 1992).

The claims are drawn to a method for modifying a plant to produce an antibody by introducing into a tobacco plant a DNA sequence encoding a heavy chain immunoglobulin or an active fragment or derivative thereof that binds to a protein present in the plant, said DNA sequence being operably linked to one or more promoters and provided, as appropriate, with an additional sequence encoding a peptide capable of targeting said antibody to a desired cellular compartment. The claims are also drawn to a plant prepared by said method, and to seeds, fruits, progeny and hybrids of said plant.

Owen et al. teach a method for modifying a tobacco plant to produce an anti-phytochrome antibody by introducing into a tobacco plant a DNA sequence encoding an antigen-binding single chain F_v protein (scF_v), said scFv comprising the heavy and light chain variable domain coding regions from a mouse monoclonal IgG1 anti-phytochrome antibody (page 790 Figure 1; page 791 column 2 second full paragraph and Figure 2; page 792 Figure 4; page 794 column 1 second full paragraph). The DNA sequence encoding the antigen-binding scFv protein taught by Owen et al. encodes a heavy chain immunoglobulin or an active fragment or derivative thereof (page 790 Figure 1; page 791 Figure 2) that binds to a phytochrome protein present in the plant (page 792 Table 1; page 793 Figure 5). The DNA sequence encoding the antigen-binding scFv protein taught by Owen et al. is operably linked to a CaMV 35S promoter (page 794 column 1 second full paragraph). Provision of an additional sequence encoding a peptide capable of targeting said antibody to a desired cellular compartment is not appropriate for the

DNA sequence encoding an antigen-binding scFv protein taught by Owen et al., as the expressed antibody was able to bind its intended antigen in the absence of a signal peptide (page 792 Table 1). The transgenic plants taught by Owen et al. are fertile and produce seed, and therefore fruit and progeny (page 792 Table 1). The transgenic plants taught by Owen et al. are also indistinguishable from the claimed hybrids, as the claims do not specifically recite any characteristics that would distinguish the hybrids from the transgenic plants taught by Owen et al.

Claims 1, 3 and 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Artsaenko et al. (The Plant Journal, Vol. 8, No. 5, pages 745-750, 1995).

The claims are drawn to a method for modifying a plant to produce an antibody by introducing into a tobacco plant a DNA sequence encoding a heavy chain immunoglobulin or an active fragment or derivative thereof that binds to a plant hormone, said DNA sequence being operably linked to one or more promoters and provided, as appropriate, with an additional sequence encoding a peptide capable of targeting said antibody to a desired cellular compartment. The claims are also drawn to a plant prepared by said method.

Artsaenko et al. teach a method for modifying a tobacco plant to produce an anti-abscisic acid antibody by introducing into a tobacco plant a DNA sequence encoding an antigen-binding single chain F_v protein (scF_v), said scFv comprising the heavy and light chain variable domain coding regions from a monoclonal antibody (15-I-C5) specific for free abscisic acid (page 748 column 2 first full paragraph). The DNA sequence encoding the antigen-binding scFv protein taught by Artsaenko et al. encodes a heavy chain immunoglobulin or an active fragment or

derivative thereof (page 745 column 2 first paragraph) that binds to abscisic acid (page 746 Figure 3(b)). The DNA sequence encoding the antigen-binding scFv protein taught by Artsaenko et al. is operably linked to a CaMV 35S promoter (page 746 Figure 1). Artsaenko et al. provide an additional sequence encoding a LeB4 signal peptide capable of targeting said antibody to the endoplasmic reticulum (page 746 Figure 1; page 747 Figure 4).

Claims 1, 3, 4, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Le Gall et al. (Applied and Environmental Microbiology, Vol. 64, No. 11, pages 4566-4572, November 1998).

The claims are drawn to a method for modifying a plant to produce an antibody by introducing into a tobacco plant a DNA sequence encoding a heavy chain immunoglobulin or an active fragment or derivative thereof that binds to a protein present in the plant or to a plant pathogen, said DNA sequence being operably linked to one or more promoters and provided, as appropriate, with an additional sequence encoding a peptide capable of targeting said antibody to a desired cellular compartment. The claims are also drawn to a plant prepared by said method.

Le Gall et al. teach a method for modifying a tobacco plant to produce an anti-stolbur phytoplasma antibody by introducing into a tobacco plant a DNA sequence encoding an antigen-binding single chain F_v protein (scF_v), said scFv comprising the heavy and light chain variable domain coding regions from a monoclonal IgG1 antibody (2A10) directed against the major membrane protein of the stolbur phytoplasma (page 4567 column 2 second full paragraph; page 4568 column 2). The DNA sequence encoding the antigen-binding scFv protein taught by Le Gall et al. encodes a heavy chain immunoglobulin or an active fragment or derivative thereof

(page 4567 Figure 1) that binds to stolbur-infected periwinkle extract (page 4569 Table 1). The DNA sequence encoding the antigen-binding scFv protein taught by Le Gall et al. also binds to a protein present in the plant, as transgenic plants are protected against phytoplasma infection, which occurs in the sieve tubes within the phloem (page 4570 Figure 6). The DNA sequence encoding the antigen-binding scFv protein taught by Le Gall et al. is operably linked to a CaMV 35S promoter (page 4567 Figure 1). Le Gall et al. provide an additional sequence encoding the *Erwinia carotovora* pectate lyase signal peptide (pel B) capable of targeting said antibody through the secretory pathway (page 4567 Figure 1; page 4571 column 1 second full paragraph).

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Casterman et al. (WO 94/04678, 3 March 1994, Applicant's IDS).

The claims are drawn to a method for modifying a plant to produce an antibody by introducing into a plant a DNA sequence encoding a heavy chain immunoglobulin or an active fragment or derivative thereof obtainable from camelids, said DNA sequence being operably linked to one or more promoters and provided, as appropriate, with an additional sequence encoding a peptide capable of targeting said antibody to a desired cellular compartment.

Casterman et al. teach a method for modifying a plant to produce an antibody by introducing into a plant a DNA sequence encoding a heavy chain immunoglobulin obtainable from camelids (page 33 first paragraph). While Casterman et al. do not explicitly teach specific promoters or signal peptides, such promoters or signal peptides are taught implicitly, given that on page 33 Casterman et al. explicitly refers to the method taught by Hiatt et al. (Nature Vol. 342

pages 76-79, 1989), in which a specific promoter and signal peptide were used (page 76 column 2 first full paragraph after the abstract).

Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Artsaenko et al. (The Plant Journal, Vol. 8, No. 5, pages 745-750, 1995).

Claim 9 is drawn to progeny and hybrids of a plant prepared according to the method of claim 1.

Artsaenko et al. teach tobacco plants transformed with a DNA sequence encoding an antigen-binding single chain F_v protein (scF_v) (page 748 column 2 first full paragraph). There are insufficient identifying characteristics set forth in the claims to distinguish the claimed progeny and hybrid plants from the transgenic plants of the prior art. The claims do not specifically recite a progeny or hybrid plant whereby all of the identifying characteristics of the parent plant are retained. The breeding techniques used to produce the claimed progeny and hybrid plants can result in genotypically and phenotypically different plants wherein the identifying characteristics for the resultant offspring are highly unpredictable. None of the identifying features which distinguish Applicant's plants from those of the prior art are set forth (see written description rejection *supra*). Accordingly, the claimed invention is anticipated by, or in the alternative, is obvious in view of any prior art that teaches transgenic plants. See in re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process of making the product produced by a different process, if the process of making the product fails to distinguish the two

products. Sine the Patent Office does not have the facilities to examine and compare the plant of Applicant with that of the prior art, the burden of proof is upon the Applicant to show an unobvious distinction between the claimed plant and the plant of the prior art. See In re Best, 562, F.2d 1252, 195 USPQ 430 (CCPA 1977).

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
September 8, 2002

Phuong Bui 9/9/02
PHUONG T. BUI
PRIMARY EXAMINER